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(54) **Tissue opening occluder**

(57) A tissue opening occluder comprising first and second occluder portions, each occluder portion including a frame structure and an attachment structure to attach one portion to the other portion. The frames may be utilized to constrain the tissue between the two portions enough to restrict the significant passage of blood therethrough. The frame portions may be covered by a fabric suspended from a perimeter thereof. The occluder portions are conjoined at least one point on each portion.

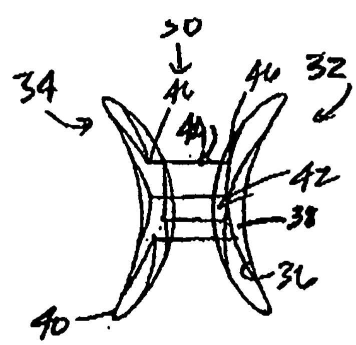

FIG. 1

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Description

[0001] The present invention generally relates to devices for occluding a tissue opening such as a patent foramen ovale (PFO) or shunt in the heart, the vascular system, etc. and particularly provides an occluder device deliverable via a catheter to the site of a tissue opening.

[0002] The device of the subject invention, in all its embodiments, may be utilized for the occlusion of many types of tissue openings, such as septal defects and PFO, and the like. For the sake of clarity, the present invention may, at times, be described specifically in the context of occlusion of a PFO. This specific description, however, should not be taken to limit the scope of the possible applications of the present invention.

[0003] The term Apatent foramen ovale@ generally refers to the failure to close a normal opening between the left and right atria (i.e., upper chambers) of the heart. Typically, a foramen ovale is a flap-like opening between the left and right atria of the heart which persists long after birth. Commonly, the foramen ovale has one flap extending from the top of the atrial chamber and another flap extending from the bottom of the atrial chamber, wherein the two flaps meet or overlap each other. Specifically, a PFO is typically located between the atrial septum primum and secundum at the location of the fossa ovalis. The opening provides a path to allow blood to bypass the lungs in an unborn infant, since the lungs are not in use during that period. The foramen ovale typically becomes functionally closed after the birth of the infant due to greater pressure from the increased blood flow in the left atrium acting upon the flap. However, in humans, for example, as many as 1 in 5 people have foramen ovale that do not fully close. In the absence of other cardiac defects or unusual cardiac pressures, the open foramen ovale does not present a substantial problem. However, in patients having circulatory problems wherein the pressure on the right side of the heart is increased, for example as the result of congenital heart disease, blood may begin to flow through the foramen ovale. This result may also occur, for example, in divers when experiencing an increase in pressure due to being under water. The presence of a significantly large PFO, a flap structure that cannot provide sufficient seal, or a significant increase in pressure can cause blood to shunt across the defect from the right atrium to the left atrium and hence on to the left ventricle, aorta, and brain. If the defect is not closed, the risk of stroke is increased. Shunting of blood from the left to the right side can also have negative consequences, such as cardiac failure or hemoptysis.

[0004] Tissue openings have traditionally been corrected by open heart surgery which required the surgeon to open the chest of a patient and bypass the heart temporarily. The surgeon would then physically cut into the heart and suture the opening closed. In the case of larger defects, a patch of a biologically compatible material would be sewn onto the tissue to cover the opening. However, the risk of complications occurring during such an intricate procedure presents substantial problems that patients would rather avoid.

[0005] In order to avoid such complications and the long recovery times associated with open heart surgery, a variety of trans-catheter closure techniques have been implemented. In such techniques, an occluding device is delivered through a catheter to the site of the tissue opening. Once the occlusion device is positioned adjacent the opening, it must be attached to the tissue wall containing the opening in a manner that permits it to effectively block the passage of blood through the opening. Furthermore, the occlusion device must also adjust to the anatomy or structure of the PFO, commonly a tunnel like structure, the width and length of which varies substantially between patients. As has been documented in the literature, the trans-catheter techniques developed thus far have had drawbacks associated therewith. For example, a variety of heretofore known devices require assembly at the situs of the tissue opening. That is to say separable or separate halves of the device are deployed and subsequently united so as to traverse or span the tissue opening in furtherance of closure. Some well known devices require threading or Abuttoning@ of the discrete device elements. Additionally, such devices require special delivery and/or deployment tools, making their utility less than desirable.

[0006] A further shortcoming in the art yet to be adequately and fully addressed is the issue of device positioning at the situs and, more particularly, re-positioning in furtherance of effectuating a proper seal of the tissue opening. Also not addressed is the ability to retrieve the device from the situs without damage thereto. Heretofore, known devices appear to evidence a broad functionality, namely that of occlusion, or more pointedly, plugging a tissue opening without a full or more developed functionality of the constituents or substructures of the device, e.g., a device which includes a single occluder reversibly secured in place by an anchor assembly.

[0007] Heretofore known self expanding devices tend to be structurally complex, expensive to produce and cumbersome to load, unload, and reliably position at the situs of a tissue opening, and insensitive to the variable requirements of the PFO tunnel geometry. The balance or tension between the structural integrity of the device, its Asize@ (e.g., bulk, rigidity, etc.), and ability to remain optimally positioned continues to be a critical consideration, cardiac devices being subject to the rhythmic pumping of the heart, on the order of 100,000 beats per day.

[0008] The present invention addresses the needs of the field, as well as other problems associated with the prior art. The present invention offers advantages over the prior art and solves problems associated therewith.

[0009] The present invention is a tissue opening occluder which preferably has first and second portions.

Both portions include a frame. One or both of the portions may have means for attaching the two portions together. Each of the frame portions is placed or positioned on one of opposite sides of a tissue wall to occlude the opening enough to restrict the significant passage of blood therethrough. One or both of the frame portions may also have a fabric support structure and have fabric suspended from a perimeter thereof. The fabric preferably is of such a type that it promotes the growth of tissue on the surface of or within the fabric. The portions may be directly attached together, attached by means of an attachment structure that is independent of either portion, may be conjoined at a single point or at a plurality of points, or may be attached by their frame and/or fabric elements. One or both of the portions may be formed in different shapes or may be identically configured.

[0010] In a first embodiment of the subject invention, the portions or halves of the occlusion device are configured as occluding panels, namely reversibly expandable elements which cooperatively engage opposing wall portions in the vicinity of the tissue defect (e.g., structures which are positioned in each atrium). Such occluding panels may be substantially planar or may have a significant third dimension. A variety of linkages are contemplated for integrating or otherwise joining the panels such that the sought after device responsiveness is obtained.

[0011] In a first alternate embodiment of the subject invention, one half of the occlusion device may be configured as an occluding panel (i.e., atrium engaging element), having two or three dimensions, while the second half may comprise a planar wire anchor structure which is configured to resiliently occupy a body structure, such as a PFO Atunnel,@ in furtherance of stabilizing the occluder panel portion of the device. The anchoring or positioning member may utilize one or more hook structures for engaging tissue surrounding the opening.

[0012] In yet a further embodiment of the subject invention, the device is adapted to be received and retained exclusively within the PFO Atunnel,@ no structure thereof extending into the atrium. The anchor structure stabilizes an occluding panel such that the panel Abridges@ the portions of the septum within the area of the defect.

[0013] In yet a further embodiment of the subject invention, the tissue opening occluder comprises eyelets wherein said eyelets are circular.

[0014] In yet a further embodiment of the subject invention, the tissue opening occluder comprises eyelets wherein said eyelets are elongate forms.

[0015] In yet a further embodiment of the subject invention, the tissue opening occluder comprises eyelets wherein said eyelets are angular forms.

[0016] The invention is directed also to a method of occluding an opening in a tissue wall, comprising the steps of collapsing an occluder assembly in a deployment catheter; positioning the catheter proximate the tissue wall to deploy a first portion of the occluder assembly with a frame of the first portion in engagement with one side of the tissue wall; and maneuvering the catheter to deploy a second portion of the occluder assembly with a frame of the second portion in engagement with an opposite side of the tissue wall and discrete points, one on each of the portions of the occluder assembly, interlinked through the opening in the tissue wall.

[0017] The invention is directed also to a method of occluding an opening in a tissue wall, comprising the steps of collapsing an occluder assembly in a deployment catheter; positioning the catheter proximate the tissue wall to deploy a first portion of the occluder assembly with a frame of the first portion in engagement with one side of the tissue wall; and maneuvering the catheter to deploy a wire frame anchor in engagement with an opposite side of the tissue wall, a discrete point on the first portion of the occluder assembly interlinked, through the opening in the tissue wall, with a discrete point on the wire frame anchor.

[0018] The invention is directed also to a method of occluding an opening in a tissue wall, comprising the steps of collapsing an occluder assembly in a deployment catheter, the occluder assembly including an occluder portion, having a frame, adapted for interposition in the opening, and a generally linearly extending anchor carried by said occluder portion, said anchor having opposite ends extending beyond said perimeter to engage the tissue wall; positioning the catheter proximate the tissue wall; and deploying the occluder assembly into the opening, wherein the ends of the anchor extending beyond the perimeter to engage the tissue wall and fix said occluder assembly in the opening.

[0019] The present invention is thus an improved device over structures known in the prior art. More specific features and advantages obtained in view of those features will become apparent from the following specification with reference to the drawing Figures

FIGS. 1 and 2 are side views of tissue opening occluders of the present invention, particularly illustrating the cooperative engagement of a pair of occluder panels;

FIGS. 3 to 9 illustrate a representative variety of operative engagements contemplated for the structures of the present invention;

FIG. 10 illustrates a side view of an anchored occluder of the subject invention sealing a PFO;

FIG. 10A is a plan view of the device of FIG. 10;

FIG. 11 illustrates the anchor structure of FIG. 10A;

FIG. 12-23 illustrate alternate embodiments of the device of FIG. 10, FIG. 13 illustrating only the anchor portion of the device in combination with linkage structure;

FIG. 24 illustrates yet a further embodiment of the tissue opening occluder of the present invention, in

side view, in a deployed condition; and,

FIGS. 25-26 illustrate embodiments of the occluder panel of FIG. 24.

[0020] As a preliminary matter, the subject invention contemplates three general configurations, several styles of each shown and subsequently described in the Figures The first general configuration for the tissue opening occluder (e.g., those illustrated in Figures 1-9) is characterized by paired occluder panels which are operatively joined so as to permit a high degree of motion, including rotation. The occluder panels are positioned within each atrium so as to Apatch@ (i.e., overlay) the septum in the vicinity of the defect, each occluder panel being in relative tension (i.e., being drawn towards each other). The second general configuration for the tissue opening occluder (e.g., that structure illustrated in Figures 10-23) is characterized by a single occluder panel, functioning in a similar capacity as heretofore described, anchored by a substantially planar wire structure positionable for retention within the Atunnel@ of the PFO (i. e., overlapping septal portions). A third configuration for the tissue opening occluder (e.g., those illustrated in Figures 24-26) is characterized by its deployed, occluding position, specifically its retention within a defect such that the device is effectively contained within a tunnel of a PFO so as to greatly reduce, if not eliminate, passage (i.e., shunting) of blood from the right to left atrium. Finally, a variety of advantageous linkages, namely those of Figures 3-9, facilitating operative engagement between the major structural elements of the several embodiments, are provided.

[0021] Referring generally to Figures 1 and 2, there is illustrated a first general configuration for the subject reversibly deployable tissue opening occluder 30 which includes first and second portions, more particularly, an occluder panel 32 and an anchor assembly 34 extending therefrom, each of these structures being intended to be opposingly paired about a tissue opening of a type as illustrated in FIG. 10. The anchor assembly 34 of this general configuration comprises a panel similar to the occluder panel, however not necessarily identical therewith, which is joined, at least indirectly, to the occluder panel 32 via a linkage 44. The occluder panel 32 includes a fabric support structure 36 and fabric 38 supported by a perimeter thereof. The fabric support structure may include the wire frame, the linkage, or both. The wire frame can be of many shapes and is preferably made of superelastic wire, preferably Nitinol. The wire frames preferably have a predetermined shape which is restored after deployment of the wire frame through a delivery catheter. The fabric is secured to the fabric support structure by suturing or other methods known in the art. The fabric is biocompatible and preferably supports tissue ingrowth so as to stabilize the implanted device at the implant site. Suitable fabrics include polyester, ePTFE, and other appropriate materials. Preferably, but not necessarily, the occluder panel 32 may embrace the panel styles disclosed in pending United States Patent Applications Serial No. 09/628,211 and Serial No. 09/760,056, and in issued United States Patent No. 6,214,029. As will be later detailed, once the occluder panel 32 is reliably positioned relative to the septal wall (e.g., within the left atrium), it may be anchored to the tissue wall via the anchor assembly 34 (i.e., positioning and deployment of the proximal anchor in abutting engagement with the septum within the right atrium), thereby eliminating the flow or shunting of blood through the opening or passageway.

[0022] Referring now to Figures 3-9, a variety of linkages 44 are illustrated for the occluder panel/anchor assembly. Each of these structures provide resilient directional translation and rotation for one half of the device with respect to the other. The key consideration is the responsiveness of the occluder panel 32 with and to, the anchor assembly 34 during engagement of the occluder panel 32 with the tissue opening.

[0023] The linkage 44 may take the form of extra winds on conjoint eyelets 46 (FIG. 3) and the eyelets may be enlarged. The linkage may include one or more fibers of material such as a suture or wire (FIG. 4-9). The suture may be a wire suture and may be made of Nitinol. The linkage 44 may more particularly include a wire structure such as a loop, coil, or spring, such as a coil spring or a leaf spring. The linkage 44 may have opposing ends terminating in loops or eyelets to facilitate connection to each of the halves of the device. Furthermore, greater than one linkage may be provided between the occluder panel 32 and the anchor assembly 34 (FIG. 7, see also FIG. 1 in which the anchor assembly is configured similarly to the occluder panel).

[0024] Referring now to Figures 10 and 10A, an alternate configuration of the tissue opening occlusion device 30 of the subject invention is illustrated in a fully deployed condition, fully engaged with portions of a tissue wall adjacent an opening or passage therethrough, (e.g., foramen ovale) so as to effectively block blood flow through the passage. The reversibly deployable tissue opening occluder 30 generally includes first and second halves, more particularly, an occluder panel 32 and an anchor assembly 34 extending therefrom. The occluder panel 32 includes a fabric support structure 36 and fabric 38 (not shown in Figures 10 and 10A) supported by a perimeter thereof. Preferably, but not necessarily, the occluder panel 32 may embrace the panel styles previously noted. As will be later detailed, once the occluder panel 32 is reliably positioned relative to the septal wall, it may be anchored to, or at least relative to, the tissue wall via the anchor assembly 34, thereby eliminating the flow or shunting of blood through the opening or passageway.

[0025] The anchor assembly 34 of Figures 10-23 generally includes a wire anchor element 40 of generally planar configuration adapted to be selectively manipulatable in furtherance of positioning and securing the occluder panel 32 at a tissue opening situs. The wire an-

chor element 40, as shown, is intended to be positioned and retained within a characteristic Atunnel@ of the PFO, as for instance by expansion of the structure into tensioned engagement with portions of the tunnel. The wire anchor element 40, as will be later discussed in detail, is at least indirectly linked to a central portion 42 of the fabric support structure 36, the occluder panel 32 and anchor assembly 34 being thereby opposingly urged into engagement with the tissue opening in furtherance of closure of the tissue opening or passage. As will become evident, it is preferred that the wire anchor element 40 have a portion configured to snugly fit against a portion of the tissue wall, and that at least a portion of the wire anchor element 40 be wide enough to anchor or set the occluder panel 32 in place despite the forces being applied to the device generally by the fluid running through the structure (e.g., heart, vessel, etc.) in which the device is placed. It is to be further understood that the wire anchor element 40 may itself be a fabric support structure (i.e., function to suspend fabric from at least a perimeter thereof), to the extent that the addition or inclusion of fabric is advantageous in furtherance of Asetting,@ in a long term sense, the anchoring assembly (i.e., pseudo-assimilation of the structure to the tissue: further adherence of the structure to the tissue) post device deployment, or advantageous in immediate closure of the passage such as by clotting.

[0026] The anchor assembly 34 of the tissue opening occluder 30 further includes linkage 44 (not shown in Figures 10 and 10A) which joins the wire anchor element 40 to or with the occluder panel 32. This linkage 44 may be integral to the wire anchor element 40, as illustrated for instance in Figures 10 and 11, or may be a separate, discrete structure, see for instance FIG. 15, which is interposed between the wire anchor element 40 and the occluder panel 32. Generally, the functionality of the linkage is to permit a resilient multidirectional (i.e., in the Cartesian coordinate sense, namely the x, y, z directional senses) spacing of the device portions. It is advantageous that the wire anchor element 40 possess a high degree of freedom with respect to its motion relative to the occluder panel 32. In addition to the aforementioned x, y, and z motion, the ability to account for rotation (i.e., torsion) is desirable. It is preferable that the linkage be capable of reversible elongation. The occluder portions 32, 34 may be attached at a single point preferably at or near the center of the occluder panel 32, or, alternatively, conjoined at a plurality of discrete points, located or positioned within the bounds or adjacent the perimeter of each of the halves 32, 34 (i.e., within an area bounded by each perimeter of the physical structures 32, 34), or on the fabric 38 as applications warrant.

[0027] As an integral component of the wire anchor element 40, the linkage 44, more particularly the physical point of connection of the occluder panel 32 to the wire anchor element 40, is preferably an eyelet 46 (i.e., a loop) as shown in Figures 1 and 2. Similarly, the central portion 42 of the fabric support structure 36 of the occluder panel 32 preferably includes eyelet 46, or a plurality of eyelets, for engaging the linkage 44 of the anchor assembly 34. It is to be understood that as used herein, the term Aeyelet@ refers generally and broadly to a loop without limitation (e.g., round, elongate, angular, single, multiple (i.e., coil), etc.). In addition to convenient connection means, the eyelets impart a further resiliency or spring-like quality to the structures into which they are incorporated, thereby fortifying the cooperative action of the anchor assembly with the occluder panel.

[0028] As is appreciated with reference to the figures, the planar wire anchor element 40 preferably, but not necessarily, has a periphery that extends out into the atria when positioned in furtherance of device anchoring. More particularly, the wire anchor element 40 is oriented substantially parallel to the tissue wall. The anchor profile should be low so that tissue can grow into the implant and so that the implant does not cause flow disturbance or facilitate clot formation. It is preferred in these embodiments, that the angle of difference between the tissue wall and the wire anchor element be less than 45 degrees, but more preferably may be less than 15 degrees. This angle of difference is preferably measured from the central axis of the tissue wall.

[0029] Anchor shapes are provided which offer capability to conform to the geometry of a PFO tunnel and resistance to inadvertent ejection from the tunnel in the direction of the occluder panel. The PFO tunnel generally ranges from 3-10 mm in width and 1-20 mm in length and is generally flat in height with no thickness under Aat rest@ conditions. Anchors such as those shown in Figures 12, 14, 16, 17, 21 and 22 offer superior ability to conform to different or variable tunnel widths. Further, the generally planar geometry of anchors shown in Figures 12-23 conform to the generally planar geometry of the PFO tunnel. Further, anchors such as those shown in Figures 14, 15, 17, 19 and 21 offer superior resistance to ejection from the PFO tunnel once fully or partially deployed in the tunnel due to a portion of the anchor frame being substantially parallel to the occluder panel (as shown in the figures). Finally, designs such as the anchor in Figures 17 and 21 provide superior accommodation of variable PFO tunnel lengths while maintaining a frame edge that, when deployed, will resist ejection from the tunnel

[0030] It is further advantageous, however not necessary, that the anchor assembly 34, more particularly the wire anchor element 40, include one or more hooks 48 (e.g., Figures 16/16A) for attachment of the anchor assembly 34 to the tissue wall. In devices so equipped, the portion of the wire anchor element 40 having the hook or hooks 48 formed therein, or extending therefrom, will extend substantially parallel to the tissue wall. The one or more hooks may be formed, carried and/or arranged on or with respect to the wire anchor element 40 in any suitable manner known in the art. For example, as

shown in Figures 16/16A, the wire anchor element 40 is formed having a hook 48 on an end opposite the attachment point of the two halves 32, 34. In this case, substantially the entire wire anchor element 40 will be generally aligned along the surface of the tissue wall (i.e., in conformity therewith) when the hook 48 thereof is engaged in the wall.

[0031] As previously noted, the occluder panel 32 comprises a fabric support structure 36 and fabric 38 supported or suspended by a perimeter thereof. The fabric support structure 36 of the occluder panel 32 is generally flexible and elastically deformable. Fabric 38, which may be formed of a thin, flexible material which can be folded and pulled taut without being damaged, is suspended or otherwise affixed to the perimeter of the fabric support structures 36. It may be desirable to provide an excess of fabric to the panel 32 or the anchor 40 so as to facilitate collapse of the fabric carrying structure into a catheter.

[0032] The fabric 38 is preferably a relatively porous material. While this may seem to contradict the purpose of the device, blood will tend to coagulate on the latticework provided by the porous material. Blood flow across the tissue opening is usually substantially blocked after minimal time passage. If so desired, the fabric 38 of the occluder panel 32 may be treated with a thrombogenic agent to speed this natural process, or may be impregnated with a biocompatible polymeric compound or the like to make it relatively impervious to fluids.

[0033] The primary purpose of using a porous fabric is to accelerate the process of permanently anchoring the device in place. The support structures hold the fabric tautly and in intimate contact with the surface of the tissue wall. This intimate contact between the tissue wall and perimeter of the occluder permits ingrowth of collagen and fibrous tissue from the tissue wall into the fabric. Over time, the membrane resting against the tissue wall will become securely anchored to the wall and be covered by a layer of endothelial cells. Elastic polymeric materials such as, for example, polyester knit, nylon, polypropylene, polytetrafluoroethylene (e.g., Teflon7), and expanded polytetrafluoroethylene (e.g., GoreTex7), as well as natural fabrics such as silk, are suitable materials for covering the fabric support structure 36 of the occluder panel 32.

[0034] To accommodate the need of the fabric support structure 36 to distort when retrieving the device 30 into a catheter, excess fabric can be provided. On an area basis relative to the support structure, an excess of fabric in the range, typically, of about 30-35 percent, and up to 50 percent, is sufficient. This range is required because the low stretch characteristics of the fabric prevent the support structure from collapsing in a manner suitable to get into the catheter. However, a 30 denier polyester knit is advantageous in that it possesses a low stretch character, is approximately 50% less bulky than known jersey style knit patterns which facilitates the use of smaller delivery catheters, and allows for the device of the subject invention to be retrieved into such catheters at forces that are not detrimental to either the catheter or the device (e.g., a 40 mm occluder may be pulled into a 12 French catheter using a reasonable peak force of about four pounds).

[0035] The fabric 38 may be attached to support structures 36, or wire anchor element 40 as the case may be, by any suitable means. For instance, the fabric 38 may be directly attached to the support structures 36 by means of an adhesive or the like, or the periphery of the fabric 38 may be wrapped about the support structures 36 and the peripheral edge attached to the rest of the fabric so as to essentially define a sleeve about the support structures 36. In the latter instance, the sleeve may fit the support structure relatively loosely so that the structure may move within the sleeve with respect to the fabric. The peripheral edge of the fabric may be affixed to the rest of the fabric sheet 38 in any suitable fashion such as by sewing. Preferably, though, the periphery of the fabric can be sewn to at least some portion of the perimeter segments of the support structures 36 using a polyester, non-adsorbable suture or the like.

[0036] The planar wire anchor element 40 and the fabric support structure 36 are preferably formed of a flexible, elastically deformable material such as a biocompatible metal, metal alloy or polymer, most preferably a superelastic material. One such material currently known in the art is a near-stoichiometric nickel/titanium alloy, commonly referred to as Nitinol or NiTi. Such superelastic materials may be elastically deformed to a much greater extent than most other materials, yet substantially fully recover their original shape when released. This permits the frame to be deformed sufficiently for insertion into, and passage through, a small-diameter catheter, yet automatically elastically return to its initial shape upon exiting the catheter.

[0037] The frame portions are preferably manufactured with nitinol wire that can be wound around the pins of a forming die and subjected to heat treatment. The wire may be bent through greater than 360 degrees to form the loops or eyelets. The ends of the wire may be attached to each other in any secure fashion, such as by means of welding, a suitable biocompatible cementitious material, or by any means known in the art. For example, the wire ends of each frame half can be connected with a titanium hypo tube using a compression crimp. Titanium is more ductile than nitinol, providing a reliable grip with excellent corrosion resistance, thereby making this method suitable for joining the ends of the material. Alternately, the preferred forms for the fabric support and/or the wire anchor element may be cut out from a sheet of such superelastic material as a single structure, by chemical etching, punching with a suitable punch and die, or any other appropriate forming method.

[0038] In order to enhance radiopacity so that the device can be viewed remotely during deployment, either the fabric support structure 36 or the wire anchor element (or both) may be provided with a radiopaque coat-

ing, such as gold or platinum. For instance, the wire may be plated with a thin layer of gold or platinum. For instance, a helically wound length of a thin radiopaque wire may be placed over the wire, alternatively, radiopaque marking bands, which are commercially available, may be employed. By placing one such band on segments of device structures, a physician can remotely visualize the frame as a plurality of small bands; when the bands are appropriately spaced from one another on a monitor, the physician knows that the frame is properly deployed. Alternatively, the fabric support structures can be made of wire with a radiopaque core.

[0039] With general reference to Figures 12-23, alternate embodiments of the tissue opening occluder 30 of the subject invention are illustrated, more particularly numerous configurations for the anchor assemblies 34 (e.g., the planar wire anchor elements 40): an Aeye@ (Figures 12 and 13); Amushroom heads@ (Figures 14, 15, 16, and 18); lobed elements (Figures 19-21); and the styles which are the subject of Figures 1, 2, 17, 22 and 23. The embodiments of Figures 15-18 show a discrete linkage 44 interposed between the occluder panel 32 and the anchor assembly 34 so as to define a non-stressed spaced apart condition for said structures.

[0040] Figures 24-26 illustrate a further embodiment of the tissue opening occluder of the present invention in a deployed configuration. Figures 25 and 26 illustrate the construction of the occluder panel 32. The panel 32 includes a fabric support structure 36 which is shown as having a plurality of eyelets 46 formed therein. A fabric swatch 38 is mounted to the fabric support structure 36 in an appropriate manner such as by means of suturing (not shown).

[0041] Figures 25 and 26 illustrate an anchor element 40. As discussed generally herein with regard to all embodiments, upon the occluder panel 32 being deployed into position within the PFO infudibulum, the anchor element 40 can be allowed to spring into an expanded configuration in which it operatively functions to hold the occluder panel 32 in position within the infudibulum.

[0042] The anchor element 40 of Figures 24-26 is a generally straight wire segment which, when to be deployed from, for example, a catheter (not shown), springs to its operational configuration at least in secure engagement with heart tissue. In some instances, however, the anchor element 40 would spring into, and pass through, the heart tissue. That is the disposition illustrated in Figure 24.

[0043] It will be understood that the fabric support structure can, in some embodiments, comprise a single continuous wire made of nitinol. A structure employing multiple nitinol sections, however, can also be utilized.

[0044] The swatch of fabric is made of any appropriate material discussed hereinbefore. In any case, the material of which it is made will function to promote tissue growth within the PFO infudibulum.

[0045] It will be understood that insertion of the occluder panel 32 into the PFO infudibulum will be accomplished in a manner known in the prior art. Typically, a nitinol fabric support structure would be positioned within a deployment catheter in a contracted configuration. After the catheter has been inserted through a patient=s vasculature to arrive at the PFO, it can be deployed in an appropriate manner known in the prior art. Appropriate deployment techniques are taught in pending United States Patent Application Serial No. 09/628,211, Application Serial No. 09/760,056 and issued United States Patent No. 6,214,029.

[0046] Although the foregoing has focused on application of the present invention to occlude atrial PFO, the invention is not limited to occluding only foramen ovale. For instance, the instant occlusion device can be used to treat atrial septal defect, ventricular septal defect, patent ductus arteriosus, or any other congenital or acquired orificial or tubular communications between vascular chambers or vessels.

[0047] While a preferred embodiment of the present invention has been described, it should be understood that various changes, adaptations and modifications may be made therein without departing from the spirit of the invention. Changes may be made in details, particularly in matters of shape, size, material, and arrangement of parts without exceeding the scope of the invention. Accordingly, the scope of the invention is as defined in the language of the appended claims.

Claims

1. An occluder for placement through an opening in a tissue wall comprising first and second occluder portions, each occluder portion including a frame structure having a perimeter, and an attachment structure for attachment of one of said portions to the other of said portions, said occluder portions being attached at at least one discrete point on each portion, said attachment structure between said first and second occluder portions being configured and disposed to constrain a portion of the tissue wall between said portions.

2. The occluder of claim 1, wherein at least one of said frame structures has fabric suspended from the perimeter of said frame structure.

3. The occluder of claim 1, wherein at least one of said frame structures is oriented, when in position adjacent a tissue wall, such that a plane defined by the frame structure is substantially parallel to said tissue wall.

4. The occluder of claim 3, wherein at least one conjoined point within both of said frame structures is defined by a loop formed in said frame structures.

5. The occluder of claim 1, wherein one of said frames

has a hook formed thereon for attachment of said frame to the tissue wall.

6. The occluder of claim 2, wherein each of said frame structures has fabric attached thereon, and wherein said fabric of each said frame structure is conjoined at a single location so as to define a center fabric attachment point for said occluder.

7. The occluder of claim 1, wherein said attachment between said two portions is provided by a single fiber of material, and preferably by a single fiber of wire material.

8. The occluder of claim 1, wherein said attachment between said two portions is provided by a plurality of fibers of material.

9. The occluder of claim 9, wherein said plurality of fibers are constructed to define two loops.

10. The occluder of claim 2, wherein said fabric comprises a polyester knit, and preferably a 30 denier polyester knit.

11. A reversibly deployable tissue opening occluder comprising an occluder panel and an anchor assembly extending therefrom, said occluder panel comprising a fabric support structure and fabric supported by a perimeter thereof, said anchor assembly comprising a planar wire anchor element adapted to be selectively manipulatable in furtherance of positioning and securing said occluder panel at a tissue opening situs, said wire anchor element being at least indirectly linked to a central portion of said fabric support structure, said occluder panel and said anchor assembly being thereby opposingly urged into engagement with the tissue opening in furtherance of closure.

12. The occluder of claim 12 wherein said anchor assembly further includes a linkage, said linkage joining said planar wire anchor element to said occluder panel.

13. The occluder of claim 11 wherein said anchor assembly further includes a linkage, said linkage interposed between said planar wire anchor element and said occluder panel.

14. The occluder of claim 11 or 13 wherein said linkage is capable of reversible elongation.

15. The occluder of claim 11 or 13 wherein said linkage comprises a suture.

16. The occluder of claim 11 or 13 wherein said linkage comprises a wire or a wire segment or a wire structure.

17. The occluder of claim 11 or 13 wherein said linkage comprises at least a single loop.

18. The occluder of claim 11 or 13 wherein said linkage comprises at least a single spring element.

19. The occluder of claim 12 wherein said fabric support structure includes at least a single eyelet.

20. The occluder of claim 19 wherein said at least a single eyelet comprises at least a single coil formed integral to said fabric support structure.

21. The occluder of claim 19 wherein at least one of said at least a single eyelet is located within said central portion of said fabric support structure

22. The occluder of claim 21 wherein said anchor assembly extends from said at least one of said at least a single eyelet is located within said central portion of said fabric support structure.

23. The occluder of claim 22 wherein said planar wire anchor element includes at least a single eyelet.

24. The occluder of claim 23 wherein the planar wire anchor element eyelet is connected to the fabric support structure eyelet.

25. The occluder of claim 24 wherein said wire anchor element includes at least a single tissue engaging hook.

26. An apparatus for occluding an opening in a tissue wall, comprising:

- an occluder portion adapted for interposition in the opening, said occluder portion including a frame defining a perimeter;
- a generally linearly extending anchor carried by said occluder portion, said anchor having opposite ends extending beyond said perimeter to engage the tissue wall and fix said occluder portion in the opening.

27. The apparatus of claim 26 wherein said anchor is integral with said frame.

28. The apparatus of claim 26 wherein said anchor and said frame are formed of nitinol or of a knit polyester.

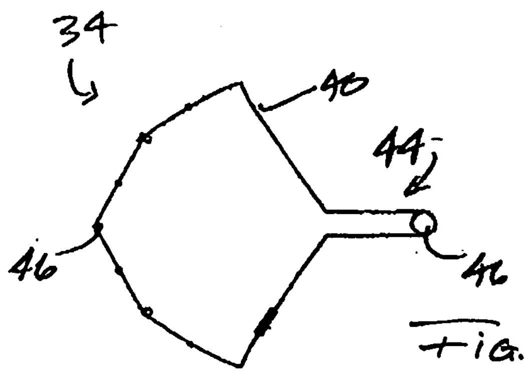

Fig. 11

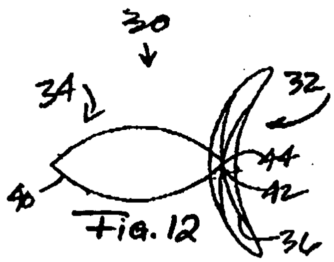

Fig. 12

Fig. 13

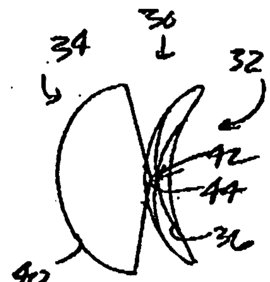

Fig. 14

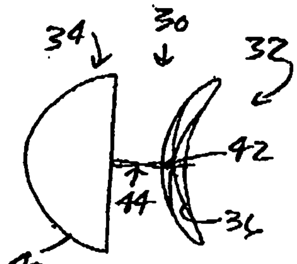

Fig 15

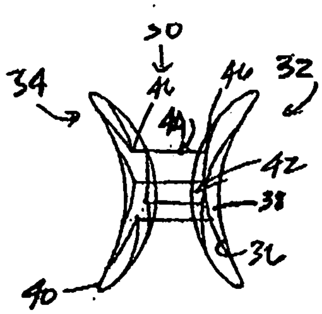

FIG. 1

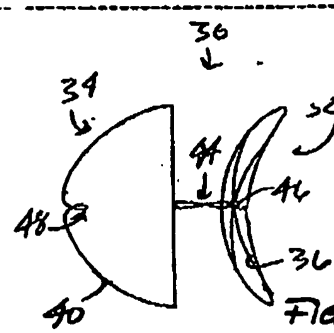

Fig. 16

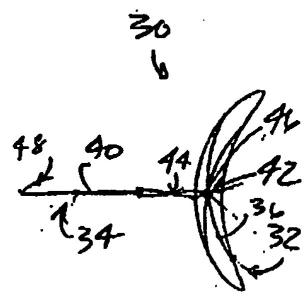

Fig. 16a

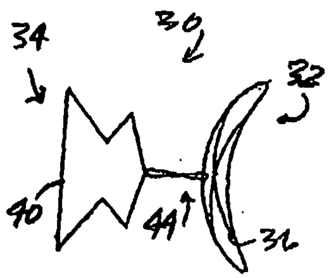

FIG. 17

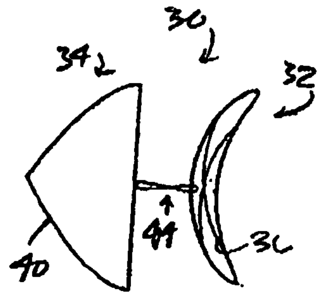

FIG. 18

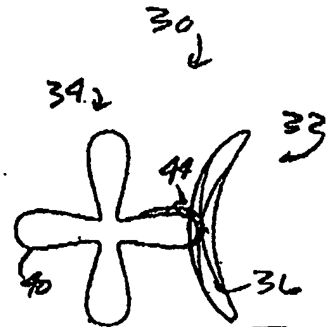

FIG. 19

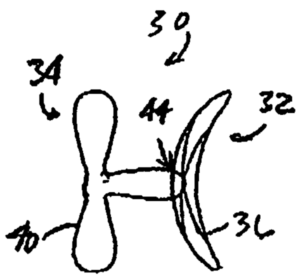

FIG. 21

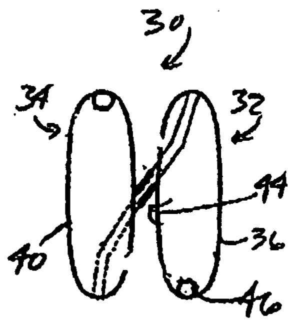

FIG. 2

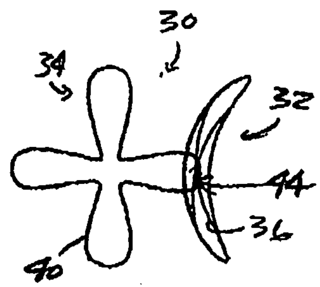

FIG. 20

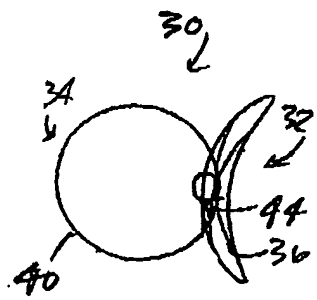

FIG. 22

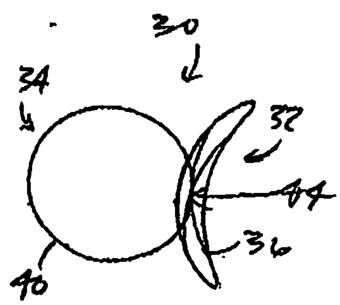

FIG. 23

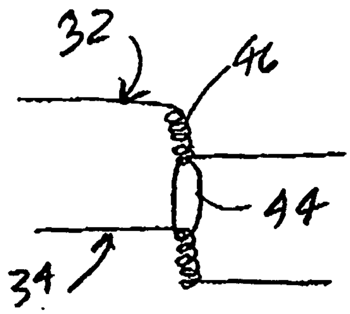

Fig. 3

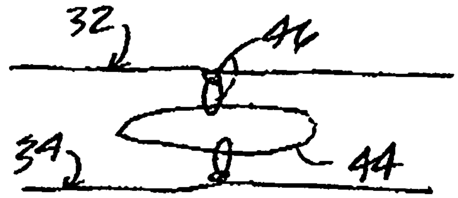

Fig. 4

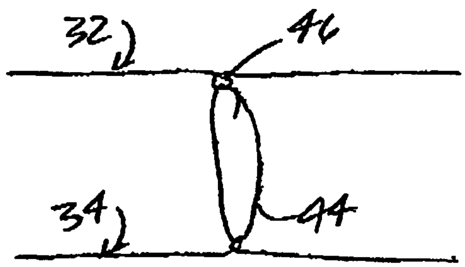

Fig. 5

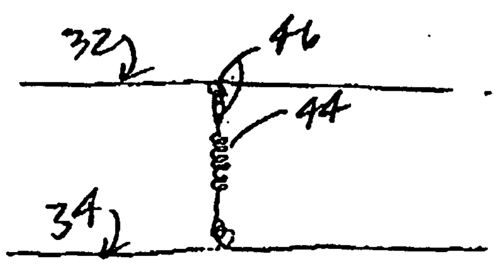

Fig. 6

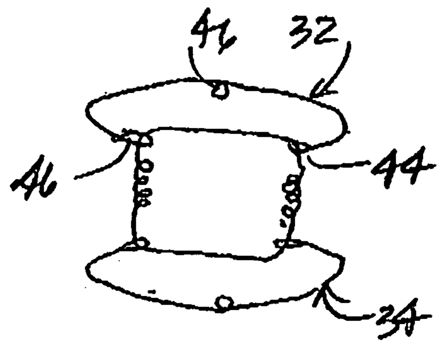

FIG. 7

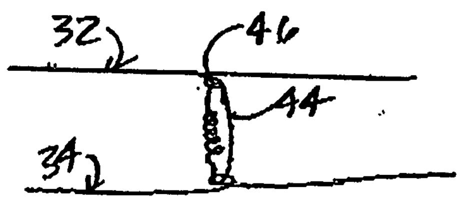

FIG. 8

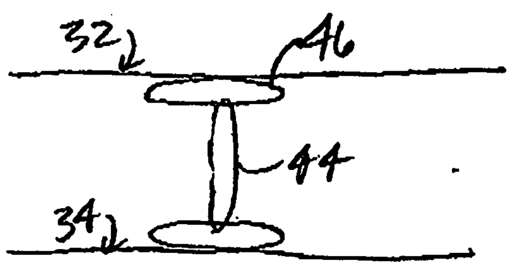

FIG. 9

FIG. 10a

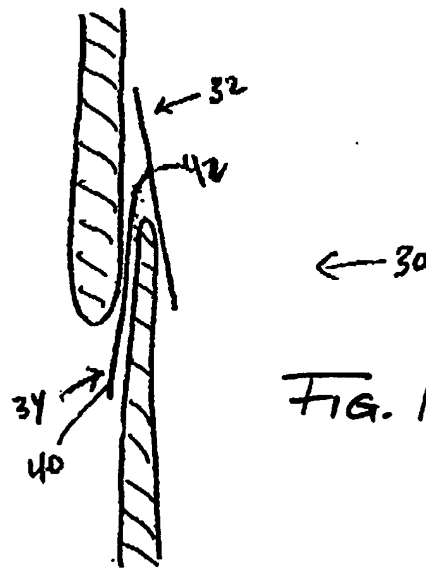

FIG. 10

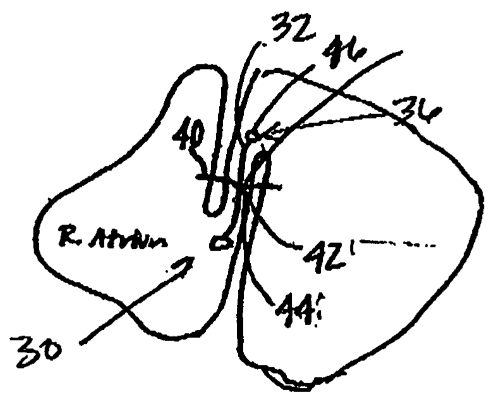

FIG. 24

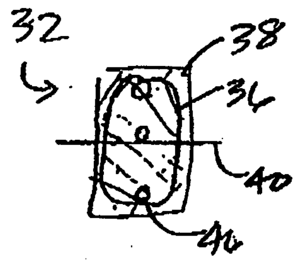

FIG. 25

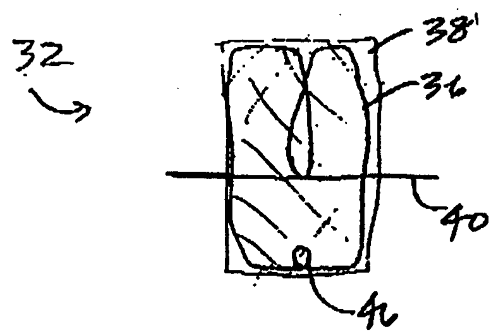

FIG. 26